## REMARKS

Claims 51-59 and 61-71 are pending. Claims 51, 52, 55-59, 62, 64, and 66-68 were amended; the amendments are supported by disclosure on, *e.g.*, page 20, lines 10-11 and page 16, lines 3-18 of the specification. New claims 69-71 are supported by disclosure on page 20, lines 10-11; and page 25 (Formulation 3).

No new matter has been added to this application.

35 U.S.C. Section 102

Claim 56 was rejected for anticipation by Paul '989. The '989 patent describes *Lactobaccillus* sp. And *Bifidobacillus* sp. The passages to which the Examiner refers (Formulation J, col. 15, lines 18-19) describes a *Bifidobacterium adolescentis*. Claim 56 has been amended to require a *Bacillus coagulans* bacterium. The '989 patent fails to describe *Bacillus coagulans*; therefore, this claim is not anticipated by the cited reference.

Claim 57 was rejected for anticipation by Reid '551. Claim 57 as amended recites in part a "suppository consisting essentially of an isolated *Bacillus coagulans* bacterium." Since Reid fails to describe *B. coagulans,* this reference does not anticipate amended claim 57.

In view of the present amendments, Applicant submits that the rejections under §102 should be withdrawn.

35 U.S.C. section 103

Claims 51-59 and 61-68 were rejected for obviousness over Hata in view of Paul and Hansen, in further view of Long and the ATCC Catalogue of Bacteria. The claims have now been amended to require that the composition contain *B. coagulans* and a supplementary enzyme

such as lactase. For example, claim 51 has been amended to recite "[a] method of increasing bioavailability of nutrients in a mammal consisting essentially of buccally administering to said mammal a composition consisting essentially of an isolated *Bacillus coagulans* bacterium, a fructo-oligosaccharide, a mineral gluconate and a supplementary enzyme selected from the group consisting of a lactase, an amylase, a glucanase and a catalase." Applicants have also amended claims 51 and 55-57 to insert the transitional phrase "consisting essentially of."

Applicant asserts that Hata teaches providing a composition containing *B. coagulans*, but do not describe a composition consisting essentially of an isolated *Bacillus coagulans* bacterium, a fructo-oligosaccharide, a mineral gluconate and a supplementary enzyme such as lactase. The amended claims are distinguished from the yogurt composition of Hata, which contains mainly milk powder.

The secondary reference Paul describes compositions containing lactic acid bacteria and fructo-oligosaccharides, but fails to describe *B. coagulans* or supplementary enzymes. The third reference, Hansen, describes making calcium–fortified yogurt using calcium gluconate and/or calcium citrate and according to the Examiner suggests the addition of fructo-oligosaccharides. Hansen also describes only *Streptococcus thermophilus* and *Lactobacilli burglarious* for yogurt culture. There is no suggestion to add a supplementary enzyme such as lactase to *B. coagulans*.

Long describes adding lactase to lactose-containing compositions such as yogurt; however, this reference fails to suggest (and the cited combination of references) fails to suggest a composition consisting essentially of a supplementary enzyme such as lactase and an isolated *B. coagulans*. The Examiner states that "Long *et al.* demonstrates that the presence of lactase in *B. coagulans* is inherent in the species." (Office Action at page 4). The amended claims now

specify that the composition contains a supplementary dietary lactase, *i.e.*, lactase in an amount that exceeds that associated with bacterial production of the enzyme. For example, claim 71 requires 200IU of lactase. The amounts of lactase required by the claims are supplemental to any lactase produced by the isolated *B. coagulans*. Therefore, the amended claims are nonobvious over Long, which teaches addinga *B. coagulans*-derived lactase to products such as yogurt.

The ATCC Calalogue teaches that *B. coagulans* was once erroneously included in the *Lactobacillus* genus. This reference does not teach or suggest the combination of a *B. coagulans* and a supplementary enzyme such as a lactase as now required by the claims. Therefore, this reference fails to add additional disclosure to the combined teaching of Hata, Long, Hansen and Paul to support a rejection for obviousness of the claims as amended.

Taken together, the cited references fail to teach or suggest the unique combination consisting essentially of an isolated *Bacillus coagulans* bacterium and a supplementary enzyme selected from the group consisting of lactase, amylase, glucanase and catalase required by the amended claims. Therefore, Applicants request reconsideration and withdrawal of the rejections under §103.

35 U.S.C. § 112

Claims 51-54, 61 and 62-68 were rejected for indefiniteness. The Examiner stated that claim 51 lacks a transitional phrase. Claim 51, as now amended, recites in part "consisting essentially of . . ."

The Examiner also stated that claim 52 is improper for failing to further limit the subject matter of claim 51. Applicant has amended claim 52 to require that the *Bacillus coagulans*

bacterium is a lyophilized vegetative cell, thereby further limiting the subject matter claimed in claim 51.

The Examiner stated that claims 61-66 are confusing in the recitation of "in the form of . . . a gel." Applicant has deleted "gel" from claims 67 and 68 and has amended claims 62, 64 and 66 to recite in part "said composition is in the form of a stabilized gel."

Accordingly, Applicant requests withdrawal of the rejections under § 112.

## CONCLUSION

On the basis of the foregoing amendments, Applicant respectfully submits that the pending claims are in condition for allowance. If there are any questions regarding these amendments and remarks, the Examiner is encouraged to contact either of the undersigned at the telephone number provided below.

A petition for extension of time and a check in the amount of $460.00 is enclosed to cover the petition fee for a three month extension of time pursuant to 37 C.F.R. § 1.17(a)(3). The Commissioner is hereby authorized to charge any additional fees that may be due, or credit any overpayment of same, to Deposit Account No. 50-0311, Reference No. 19374-504.

Respectfully submitted,

/IABeattie/

October 7, 2002

Ingrid A. Beattie, Reg. No. 42,306
Attorney for Applicants
c/o MINTZ, LEVIN
One Financial Center
Boston, Massachusetts 02111
Tel: (617) 542-6000
Fax: (617) 542-2241

Appendix: Marked up version of claim amendments

Claims 51, 52, 55-56, 62, 64 and 66-68 have been amended as follows:

51. (Twice amended) A method of increasing bioavailability of nutrients in a mammal comprising buccally administering to said mammal a composition consisting essentially of an isolated *Bacillus coagulans* bacterium, a fructo-oligosaccharide, [and] a mineral gluconate and a supplementary enzyme, wherein said enzyme is selected from the group consisting of a lactase, an amylase, a glucanase, and a catalase.

52. (Amended) The method of claim 51, wherein said [bacteria is] *Bacillus coagulans* bacterium is a lyophilized vegetative cell.

55. (Twice amended) A method of increasing bioavailability of nutrients in a mammal comprising buccally administering to said mammal a composition consisting essentially of [comprising] an isolated *Bacillus coagulans* bacterium, a fructo-oligosaccharide, [and] a mineral citrate and a supplementary enzyme, wherein said enzyme is selected from the group consisting of a lactase, an amylase, a glucanase, and a catalase.

56. (Amended) A method of increasing bioavailability of nutrients in a mammal comprising buccally administering to said mammal a composition consisting essentially of [comprising a lactic acid-producing bacteria] an isolated *Bacillus coagulans* bacterium, a fructo-oligosaccharide, and a lactase.

57. (Amended) A method of increasing bioavailability of nutrients in a mammal comprising administering to said mammal a suppository, said suppository consisting essentially of [comprising a lactic acid-producing bacteria] an isolated *Bacillus coagulans* bacterium.

58. (Amended) A composition consisting essentially of [comprising] a *Bacillus coagulans*, a fructo-oligosaccharide, [and] a mineral gluconate and a supplementary lactase.

59. (Amended) A composition consisting essentially of [comprising] a *Bacillus coagulans*, a fructo-oligosaccharide, [and] a mineral citrate and a supplementary lactase.

62. (Amended) The method of claim 51, wherein said composition [bacterium] is in the form of a stabilized gel or paste, or a stabilized liquid suspension.

64. (Amended) The method of claim 55, wherein said composition [bacterium] is in the form of a stabilized gel or paste, or a stabilized liquid suspension.

66. (Amended) The method of claim 57, wherein said composition [bacterium] is in the form of a stabilized gel or paste, or a stabilized liquid suspension.

67. (Amended) The method of claim 51, wherein said composition is a [gel] suspension, aerosol spray, capsule, tablet, wafer, powder, or semi-solid formulation.

68. (Amended) The method of claim 55, wherein said composition is a [gel] suspension, aerosol spray, capsule, tablet, wafer, powder, or semi-solid formulation.

New claims 69-71 were added as follows:

69. (New) A composition consisting essentially of an isolated *Bacillus coagulans* and a supplementary lactase.

70. (New) A composition consisting essentially of an isolated *Bacillus coagulans* spore and a supplementary lactase.

71. (New) The composition of claim 69, wherein said composition comprises 200 IU of lactase.